

PATENT ATTORNEY DOCKET NO. 50195/008003

| Certificate of Mailing: Date of | Deposit: November | 1. 2005 |
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| Continuate of Manning. Date of | | 1, 2000 |

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Colleen Coyne

Printed name of person mailing correspondence

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

James M. Robl et al.

Art Unit:

1632

Serial No.:

09/988,115

Examiner:

D. Crouch

Filed:

November 16, 2001

Customer No.:

21559

Title:

TRANSGENIC BOVINE COMPRISING HUMAN

IMMUNOGLOBULIN LOCI AND PRODUCING HUMAN

IMMUNOGLOBULIN

Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) set forth on the Issue Notification mailed on October 21, 2005 in connection with the above-captioned patent application, Applicants hereby request reconsideration of the patent term adjustment. Applicants submit that the current patent term adjustment should be 59 days (i.e., a 260 day period of Patent Office delay reduced by a 201 day period of Applicant delay as detailed below).

In support of this application, Applicants first summarize crucial dates and actions

that resulted in patent term adjustment. The present application was filed on November 16, 2001 and the first action under 35 U.S.C. § 132, a Restriction Requirement, was not mailed until September 11, 2003. The mailing of the restriction requirement was 238 days later than fourteen months from the filing date of the application, resulting in 238 days of patent term adjustment. 37 CFR 1.703(a)(1). A second Restriction Requirement was then mailed March 9, 2004, 22 days later than the four month period allowed for a subsequent PTO Action. 37 CFR 1.703(a)(2). The total Office delay was therefore 260 days, as correctly indicated by PAIR (copy enclosed).

Applicant delay occurred in connection with three submissions. A Reply to a non-final Office Action of July 29, 2004 was submitted on January 31, 2005, a delay of 94 days. A Reply to a final Office Action of April 20, 2005 was submitted on August 5, 2005, a delay of 16 days. And a Reply to Notice of Missing Parts of December 4, 2001 was submitted on June 3, 2002, a delay of 91 days, resulting in a total Applicant delay of 201 days.

It is the calculation of Applicant delay by the PTO with which Applicants disagree. As indicated on the accompanying PAIR summary, the Office has assessed a delay of 155 days for Applicants' Reply to the Notice of Missing Parts mailed December 4, 2001. This calculation is in error. The Notice of Missing Parts mailed December 4, 2001 required the submission of a sequence listing, executed inventor declarations, and substitute drawings. The executed declarations and substitute drawings were submitted

on June 3, 2002 and account for a 91 day Applicant delay. The remaining submission, the sequence listing, was mailed by Applicants on February 7, 2002 and date-stamped as received by the PTO on March 11, 2002. A copy of the date-stamped postcard is enclosed; PAIR does not indicate receipt of this submission. On June 24, 2002, the Office mailed a further Notice to Comply with Sequence Listing Requirements, indicating that Applicants' sequence diskette was "Damaged." Given the timing of this submission, this damage likely resulted from security procedures at the PTO and was not the result of Applicant error or delay. Also, the indication in PAIR that this mailing was due to "SEQUENCE ERRORS" is incorrect, as the Office required a new submission solely due to the damaged diskette. As Applicants provided a new diskette on August 6, 2002, no Applicant delay should be assessed in connection with any of the sequence listing submissions. The PAIR indication of 155 days of Applicant delay in connection with the Reply to Notice to File Missing Parts is in error and should instead be 91 days.

In addition, the Office has assessed a 58 day period of Applicant delay in connection with the filing of an Information Disclosure Statement on June 9, 2004. This assessment of Applicant delay is also in error, as this IDS was timely filed and was not submitted either less than one month before the mailing of an Office Action (which occurred on July 29, 2004), after the filing of a substantive reply (which occurred on January 31, 2005), after a decision by the Board of Appeals, or after a notice of allowance (which occurred on October 21, 2005). 37 CFR 1.704(d). It appears that the Office may

have inadvertently confused Applicants' Reply to the second Restriction Requirement

with a Reply to a first substantive Office Action. This assessment of 58 days of

Applicant delay should be withdrawn.

In addition, Applicants note that the present patent is not subject to a Terminal

Disclaimer.

CONCLUSION

Applicants submit that the current patent term adjustment should be 59 days and

request reconsideration of the patent term adjustment.

Enclosed is a check in the amount of \$200.00 for the fee set forth in 37 C.F.R.

§ 1.18(e). If there are any additional charges or any credits, please apply them to Deposit

Account No. 03-2095.

Respectfully submitted,

Date: 01 No ratou 2005

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Reg. No. 35,238

Clark & Elbing LLP 101 Federal Street

Boston, MA 02110

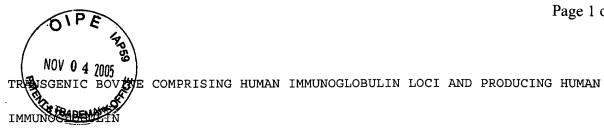
Telephone: 617-428-0200

Facsimile: 617-428-7045

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Printer Friendly `09/988,115



Patent Term Adjustment History

| Patent Term Adjustment (PTA) for Application Number: 09/988,115 | | | | | | |
|---|---|--------------------|-------------|--------------|-----------|------------|
| | | | | | | Days |
| Fili | ing or 371(c) Date: | 11-16-2001 | US | PTO Delay (| PTO): | 260 |
| Is | sue Date of Patent: | - | | Three ` | Years: | |
| Pre-Issu | ue Petitions (days): | +0 | Appli | cant Delay(A | PPL): | 323 |
| Post-Issu | ue Petitions (days): | +0 | | Total | PTA: | 0 |
| USPTO | Adjustment(days): | +0 | Explanation | of Calculat | ions | |
| | Patent | Term Adjust | ment Histor | y | | |
| Date | Conte | nts Descriptio | n | PTO(Days) | AP (Da | PL lys) |
| 10-21-2005 | Mail Notice of Al | lowance | | | | |
| 10-21-2005 | Mail Examiner's A | Amendment | | | | |
| 10-04-2005 | Issue Revision Co | mpleted | | | | |
| 10.04.2005 | Eveniner's Amen | dment Commi | ınication | | | |
| 10-04-2005 | Notice of Allowar Completed | nce Data Verifi | cation | | | - |
| 09-23-2005 | 23-2005 Miscellaneous Incoming Letter | | | | | |
| | Date Forwarded to | | | | | |
| 08-15-2005 | Date Forwarded to | Examiner | | | | |
| 08-15-2005 | DISPOSAL FOR abandonment if CI | A RCE/CPA/1 PA) | 29 (express | | | |
| 08-05-2005 | 8-05-2005 Information Disclosure Statement considered | | | | | |
| 08-05-2005 | Request for Continued Examination (RCE) | | 仓 | | 16 | |
| 08-05-2005 | Request for Exten | sion of Time - | Granted | ተ | | 仓 |
| 08-05-2005 | 2005 Reference capture on IDS | | Û | | 仓 | |
| 08-05-2005 | 05-2005 Information Disclosure Statement (IDS) Filed | | | | 介 | |
| 08-05-2005 | 8-05-2005 Workflow - Request for RCE - Begin | | 1 | | 1 | |
| 04-20-2005 | Mail Final Rejecti | on (PTOL - 32 | 26) | 1 | · | 介 |
| 04-18-2005 Final Rejection | | 1 | | | | |
| 02-11-2005 | 02-11-2005 Date Forwarded to Examiner | | 1 | | | |
| 01-31-2005 | -2005 Information Disclosure Statement (IDS) Filed | | | | | |
| 01-31-2005 | Response after Non-Final Action | | 介 | | 94 | |
| 01-31-2005 | 5 Request for Extension of Time - Granted | | 仓 | | 1 | |
| 01-31-2005 | 005 Workflow incoming amendment IFW | | Ŷ | | 4 | |
| 07-29-2004 | 29-2004 Mail Non-Final Rejection | | 企 | | 1 | |
| 07-26-2004 | Non-Final Rejection | | 仓 | | | |
| 06-09-2004 | Information Disclosure Statement (IDS) Filed | | | ì. | 58 | |
| 05-18-2004 | Date Forwarded to Examiner | | 介 | | 1 | |
| 04-12-2004 Response to Election / Restriction Filed | | 个 | | 仓 | | |
| 04-12-2004 | Workflow incomi | ng amendment | IFW | 仓 | | |
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| 04-05-2004 Preliminary Ar | nendment | ı | 1 |
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| 04-05-2004 Workflow inco | | 4 | |
| 03-09-2004 Mail Restrictio | | 22 | - |
| 03-06-2004 Requirement for | | 4 | |
| 01-20-2004 Date Forwarde | | 1 | |
| 12-17-2003 Correspondence | | 1 | |
| 10-16-2003 Response to El | | 1 | |
| 09-11-2003 Mail Restrictio | | 238 | |
| 09-11-2003 Requirement for | | Û | |
| 10-16-2002 Case Docketed | | Ŷ | |
| 09-03-2002 Application Di | | 1 | |
| 08-26-2002 Application Is | | Ŷ | |
| | echnically / Entered into | ſr | |
| 08-06-2002 Additional App | olication Filing Fees | 4 | 155 |
| | Been Received by Preexam / | Ŷ | ተ |
| 07-18-2002 Request for Re | fund | Ŷ | |
| 06-24-2002 SEQUENCE E | | Û | 1 |
| | Been Received by Preexam / | ① | 仓 |
| 06-03-2002 Additional App | | 4 | 介 |
| | ls and procedures, provided to | 1 | |
| A statement by 06-03-2002 satisfying the re | one or more inventors equirement under 35 USC 115, | û | Û |
| 06-03-2002 Applicant has s | submitted new drawings to ed Papers problems | Û | 1 |
| OZ 28 2002 CRF Does Not | Match Application Applicant Must Correct | Û | 1 |
| | ACR Auto Security Review | 企 | 仓 |
| 12-04-2001 Notice Mailed- Filing Date Ass | -Application Incomplete igned | ₽ | ① |
| 11-29-2001 Correspondence | e Address Change | 介 | |
| | ACR Auto Security Review | 企 | |
| 11-16-2001 Initial Exam To | eam nn | Û | |

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| **PROSECUTION** | PATENT ATTORNEY DOCKET NUMBER: | 50195- | 008003 |
|---|--------------------------------------|----------------|---------------------|
| The U.S. PTO date stamp sets fort | | IPE | ^ |
| Applicant/Patentee: James | M. Robl et al. | /6 | 3 |
| Serial/Patent Number: 09 9 | 38,115 | MAR 1 1 2002 | 3 |
| Filed/Issued: Novembe | | P. C. | * |
| Title: Expression Of | Xenogenous (Hi | un sent a sent | im unoglobin |
| | es: □ Declaration & POA | | Pages: |
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| | es: □ Change of Address | | Pages: |
| Reply to Examiner's Action Page | | • | Pages: |
| □ Extension of Time Page | es: □ Preliminary Ameno es: □ IDS | ament | Pages: Pages: |
| □ Notice of Appeal Page □ Appeal Brief Page | es: □ Cited References | 0.1 | Number: |
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| a Sequence Statement Page | 25: aL | · J | |
| Other Sequence Listing | a ' | | Pages: 17 |
| Atty/Secy: KLE MK Client/M | ^ | · | Date: <u>2-7-02</u> |
| (VLH) | | | |